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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,442	01/24/2001	Chun-Ying Huang	U 012951-1	2379

7590

05/24/2004

Ladas & Parry
26 West 61st Street
New York, NY 10023

EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/768,442	Applicant(s) HUANG ET AL.	
	Examiner Michael G. Hartley	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/2003 has been entered.

Response to Amendment

The amendment filed 1/20/2004 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Patt et al (Am. Jour. Clin. Oncol., 2000, PTO-1449,AN).

Patt et al. a method of treating hepatocellular carcinoma comprising administering a thalidomide pharmaceutical composition, see pages 319-320. The dosage used was from 400mg to 1,200 mg/day, see page 320, which is directly within the scope of the claimed dosage range.

Claims 9-11 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Das (US 6,617,354).

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Das discloses a method of treating hepatocellular carcinoma (hepatoma) comprising administering a thalidomide pharmaceutical composition, see claims 1-4. The dosage of the anticancer agents (i.e., thalidomide) is about 1 to 100 mg, see column 12.

Claims 9-11 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Lentz (US 6,231,536).

Lentz discloses a method of treating hepatocellular carcinoma (liver metastases) comprising administering a thalidomide pharmaceutical composition, see example 4, column 8. The dosage of the thalidomide is 200 mg, see example 4, which is directly within the scope of the claimed dosage range.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Amato (US 5,629,327) and Masiero (reference) and Patierno (US 5,696,092), for the reasons set forth in the office action mailed 11/21/2002.

Response to Arguments

Applicant's arguments filed 1/20/2004 have been fully considered but they are not persuasive.

Applicant asserts that none of the references teach the treatment of hepatocellular carcinoma with thalidomide and because of the diversity of different cancers one of ordinary skill in the art would not have a expectation of success in treating this cancer with thalidomide from the three cited references.

This is not found persuasive because obviousness does not require absolute predictability. D'Amato provides a disclosure that thalidomide can be used to treat various cancers that have angiogenic behavior (e.g., that thalidomide is an anti-angiogenesis agent), while Masiero specifically teaches that thalidomide is used to treat prostate and breast cancer. Patierno teaches that liver cancers are

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specifically treatable with anti-angiogenesis agents and that such cancers respond in a similar fashion to such agents as compared to prostate cancer, etc, see columns 8-9. Thus, one of ordinary skill in the art would be motivated to employ the thalidomide disclosed as an anti-angiogenesis agent by D'Amato and as an anticancer agent by Masiero in various related cancers because it is known in the art that liver cancers (e.g., hepatocellular carcinoma) respond well to such anti-angiogenesis agents, thereby providing a useful treatment for such cancers with a reasonable expectation of success. One of ordinary skill in the art of cancer treatment would have been motivated to use the anti-angiogenesis agent thalidomide as disclosed by D'Amato to its fullest potential to treat any cancers that respond to such agents.

The declaration under 37 CFR 1.132 filed 11/12/2003 is insufficient to overcome the rejection of claims 9-11 based upon over D'Amato (US 5,629,327) and Masiero (reference) and Patierno (US 5,696,092) as set forth in the last Office action because: This declaration only provides a general opinion that various cancers are diverse and that no medicine is expected to treat all types of cancers. And that certain drugs have only received approval (e.g., FDA) in specific cancers. It is agreed upon that cancer is a diverse disease. However the references cited in this rejection deal with related cancers and related ways of treating such cancer, i.e., using an anti-angiogenesis agent. One only needs a reasonable expectation of success for obviousness. FDA approval is separate issue from patentability and such approval is not a prerequisite for showing that references provide an obviousness teaching.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in R.O.C. on 2/2/2000. It is noted, however, that applicant has not filed a certified copy of the 89101826 application as required by 35 U.S.C. 119(b).

Conclusion

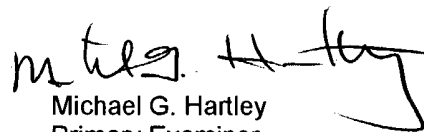
No claims are allowed at this time.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "m. g. hartley", with a stylized flourish at the end.

Michael G. Hartley
Primary Examiner
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5/20/2004